REMARKS

Claims 40, 42, 43, 103, and 111-148 were pending in the application. Claims 40, 42, 43, 103, 111-115, 118, 120, 121, 123, 125, 127-129, 133, 135, 137, 139-141, 144, and 146 have been amended. Claims 149-151 have been added. Support for newly added claims is found in Examples 32 and 33, at pages 88-89. No new matter has been added. No claim has been canceled. Thus, upon entry of the instant amendments, claims 40, 42, 43, 103, and 111-151 will be pending in this application. For the Examiner's convenience, a copy of all claims pending after entry of these amendments is included with this Reply.

In the Office Action mailed May 23, 2001, claims 121, 135 and 146 were withdrawn from consideration, as being drawn to a nonelected species. Applicants have amended claims 121, 135 and 146 to recite the elected species of these claims, namely, demineralized bone. Applicants thus respectfully request consideration of claims 121, 135, and 146, as amended and drawn to the elected species.

The Office Action also states that "Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119 or § 120." Office Action at 2. Specifically, the Office Action states:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 C.F.R. 1.78).

Id. Applicants have complied with this requirement by amending the specification accordingly in this Reply.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 40, 42, 43, 103, 111-120, 122-134, 136-145, 147 and 148 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As grounds for this rejection, the Office Action states:

> "Compact", "Promoter", "Predetermined", "Strongly", "Poorly", "intimate", "supplemental", "selected", "characteristic" are all indefinite, ambiguous or relative terms, and fail to impart specificity to permit identification of the meets [sic] and bounds of the subject matter of the invention as it is claimed. So is "suitable", "associated with", "derivativized". There is no antecedent for "conversion" of claim 111.

Office Action at 3. For the sake of clarity, applicant will first discuss the appropriate standard under 35 U.S.C. § 112, second paragraph, and then address each amended claim and the bases for these rejections.

As the MPEP explains:

> A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim, which makes clear the boundaries of the subject matter for which protection is sought. As noted by the Court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), ***a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.***
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> * * *
>
> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, ***in light of the specification***.

MPEP §§ 2173.01, 2173.05(b) (7th ed., Rev. 1)(emphases added). Thus, the bare assertion that certain claim language uses "relative terms" is insufficient to support a rejection of claims as indefinite under 35 U.S.C. § 112, ¶2. Rather, the pertinent inquiry is whether one of ordinary skill in the art would understand what is claimed, in light of the specification. Because the Office Action fails to consider the specification, and improperly rejects the claims because of the type of language used to define the subject matter, the rejections under 35 U.S.C. § 112, 12, should be withdrawn.

Claims 40, 43, 103, 114, 115, 127, and 140 were amended to change, *inter alia*, the claim term "powder compact" to "compressed object." Support for this amendment is found throughout the application as filed, for example, at pages 61-64 and 88-92 of the application. Applicants submit that this amendment obviates the rejection of these claims under 35 U.S.C. § 112, ¶2, with respect to the word "compact."

The word "promoter," as used in the pending claims, is sufficiently definite to satisfy the requirements of 35 U.S.C. § 112, ¶2. As explained in the application, the term "promoter" refers to "a material or treatment that promotes hardening of a hydrated precursor" and may enhance the conversion of amorphous calcium phosphate to poorly crystalline apatitic calcium phosphate. *See* page 8, lines 21-25. Furthermore, as explained exhaustively in the application:

> *Types of Promoters.* The purpose of the promoter is to promote the hardening of the hydrated precursor and preferably to accelerate the conversion of ACP to a PCA calcium phosphate. Any material or method which serves this purpose is considered to be with in the scope of the reaction. This includes the limited case where hardening occurs in the absence of conversion, that is when a PCA calcium phosphate precursor is used as the starting material.
>
> With respect to the conversion of ACP, a promoter may promote the overall reaction or any intermediate reactions involved in the conversion or hardening process. In this regard preferred promoters will reduce the activation energy for one or more specific steps in the conversion or hardening process.
>
> The promoter used to convert a reactive ACP to the inventive PCA calcium phosphate may itself be converted to PCA calcium phosphate calcium phosphate or otherwise participate in a chemical or physical reaction during the conversion process. Such promoters are referred to herein as "participating".
>
> Alternatively a promoter may remain substantially unchanged during the reactive ACP conversion serving essentially to catalyze or to initiate or enhance PCA nucleation and hardening. These promoters are referred to as "passive" promoters.
>
> Promotion of the hardening and conversion of a reactive ACP to PCA calcium phosphate through the use of other means such as the use of heat, pressure, reaction gases, solvents, ionic solutions, or radiochemistry is also considered within the scope of the invention. Such promoting means are termed reaction enhancing or "enhancing" promoters.
>
> Promoters may have different abilities or strengths in the promotion of the production or a hardened PCA calcium phosphate from ACP. Likewise, not all ACPs are equally reactive. Thus weak promoters will not always be effective in reacting with ACPs with low reactivity. In such circumstances stronger promoters will be preferred. Promoter strength may conveniently be tested by comparing the reactivity of a given promoter with the preferred carbonated ACP

> of the invention in both its heat activated highly reactive form as well as its non-heat activated form using the method described in Example 8. The use of hand mixing of reactants is particularly suited for identification of highly reactive promoters. Less reactive promoters may benefit from mixing in an automated mill as described in Example 9. By use of these methods DCPD with the grain size distribution of B1 in example 10 was demonstrated to be a weak promoter, where as grain sizes in the range of <100 μm were found to be strongly reaction promoting.
>
> In addition to the guidance given above for the matching of a particular promoter to a given ACP, such matching may be done empirically by mixing a given ACP with a selected promoter in the presence of about 1.0 mL water/g powder and heating the mixture at 37 °C in a moist environment. A suitable promoter exhibits PCA calcium phosphate formation and paste hardening under these conditions.

Page 18, line 19 - page 19, line 30. Accordingly, Applicants respectfully submit that the claim term "promoter" satisfies the requirements of 35 U.S.C. § 112, ¶ 2.

The Office Action has also rejected claims that use the word "predetermined," on the basis that this word is "indefinite, ambiguous, or relative" and fails "to impart specificity to permit identification of the meets [sic] and bounds of the subject matter of the invention as claimed." Office Action at 3. Applicants respectfully submit that the word "predetermined," as used in the pending claims is sufficiently definite to satisfy the requirements of 35 U.S.C. § 112, ¶ 2. As used in the pending claims, "predetermined" is used to refer to a "predetermined shape." The present application clearly explains that the invention includes compressing "converted PCA granules into a desired shape." Page 61, lines 9-10. The inventors further explain that:

> The solid PCA calcium phosphate material can be used in many different applications, depending on the details of the situation. The first application applies to orthopedic implants. Pellets, plates, screws, granules, bone void fillers, and other forms are appropriate for orthopedic applications. The pellets, plates, and screws can be of various shapes and sizes.

Page 63, lines 8-12. Thus, it is clear that one of ordinary skill would understand Applicants' the meaning of "predetermined shape," as used in the pending claims. Accordingly, Applicants respectfully submit that the claim term "predetermined" satisfies the requirements of 35 U.S.C. § 112, ¶ 2.

The Office Action has also rejected claims that use the word "strongly," on the basis that this word is "indefinite, ambiguous, or relative" and fails "to impart specificity to permit

identification of the meets [sic] and bounds of the subject matter of the invention as claimed." Office Action at 3. Applicants respectfully submit that the word "strongly," as used in the pending claims is sufficiently definite to satisfy the requirements of 35 U.S.C. § 112, ¶2. As used in the pending claims, "strongly" is used to refer to "strongly bioresorbable" which is clearly defined in the application as meaning "that at least 80%, preferably 95-99%, and most preferably > 99%, of the total mass of material implanted intramuscularly or subcutaneously is resorbed within one year." Page 7, lines 13-16. Thus, one of ordinary skill would understand the meaning of this term from simply reading Applicants' specification. Accordingly, Applicants respectfully submit that the claim term "strongly," as used in the pending claims, satisfies the requirements of 35 U.S.C. § 112, ¶ 2.

The Office Action has also rejected claims that use the word "poorly," on the basis that this word is "indefinite, ambiguous, or relative" and fails "to impart specificity to permit identification of the meets [sic] and bounds of the subject matter of the invention as claimed." Office Action at 3. Applicants respectfully submit that the word "poorly," as used in the pending claims is sufficiently definite to satisfy the requirements of 35 U.S.C. § 112, 12. As used in the pending claims, "poorly" is used to refer to "poorly crystalline apatitic calcium phosphate." This term is clearly defined in the application as follows:

> The PCA material is not necessarily restricted to a single calcium phosphate phase provided it has the characteristic XRD and FTIR pattern. A PCA calcium phosphate has substantially the same X-ray diffraction spectrum as bone. The spectrum is generally characterized by only two broad peaks in the region of 20-35° with one centered at 26° and the other centered at 32°. It is further characterized by FTIR peaks at 562 cm^{-1}, 1034 cm^{-1}, 1638 cm^{-1} and 3432 cm^{-1} (± 2 cm). Sharp shoulders are observed at 603 cm^{-1} and 875 cm^{-1}, with a doublet having maxima at 1422 cm^{-1} and 1457 cm^{-1}.

Page 8, lines 12-20. Thus, it is clear that one of ordinary skill would understand Applicants' the meaning of "poorly crystalline apatitic calcium phosphate," as used in the pending claims. Accordingly, Applicants respectfully submit that the claim term "poorly," as used in the pending claims, satisfies the requirements of 35 U.S.C. § 112, ¶2.

Applicants have amended claim 42 by deleting the word "intimate." Accordingly, the rejection based on this claim term is now moot.

The Office Action has also rejected claims that use the word "supplemental," on the basis that this word is "indefinite, ambiguous, or relative" and fails "to impart specificity to permit identification of the meets [sic] and bounds of the subject matter of the invention as claimed." Office Action at 3. Applicants respectfully submit that the word "supplemental," as used in the pending claims is sufficiently definite to satisfy the requirements of 35 U.S.C. § 112, ¶2. As used in the pending claims, "supplemental" is used to refer to "supplemental materials." Yet again, this term is exhaustively defined in the application:

> The composite material of the present invention is prepared by combining the PCA calcium phosphate of the invention with a selected supplementary material. The PCA calcium phosphate may serve as the reinforcing material, the matrix or both. The PCA calcium phosphate of the invention in it's [sic] initial paste form (i.e., as a hydrated precursor) typically maintains a pH of about 6-7 and is therefore compatible with a wide range of additives without deleterious effect. The supplementary material is selected based upon its compatibility with calcium phosphate and its ability to impart properties (biological, chemical or mechanical) to the composite, which are desirable for a particular therapeutic purpose. For example, the supplementary material may be selected to improve tensile strength and hardness, increase fracture toughness, alter elasticity, provide imaging capability, and/or alter flow properties and setting times of the PCA calcium phosphate.
>
> The supplementary material may be added to the PCA calcium phosphate in varying amounts and in a variety of physical forms, dependent upon the anticipated therapeutic use. By way of example only, the supplementary material may be in the form of sponges (porous structure), meshes, films, fibers, gels, filaments or particles, including micro- and nanoparticles. The supplementary material itself may be a composite. The supplementary material may be used as a particulate or liquid additive or doping agent which is intimately mixed with the resorbable PCA calcium phosphate. The supplementary material may serve as a matrix for the PCA calcium phosphate, which is embedded or dispersed within the matrix. Alternatively, the PCA calcium phosphate may serve as a matrix for the supplementary material, which is dispersed therein. The supplementary material may be applied as a coating onto a PCA calcium phosphate body, for example, as a post-fabrication coating to retard resorption time or otherwise affect the bioceramic material properties. Lastly, the supplementary material may be coated with PCA calcium phosphate.
>
> The supplementary materials are desirably biocompatible, that is, there is no detrimental reaction induced by the material when introduced into the host. In many instances, it is desirable that the supplementary material also be bioresorbable. In many preferred embodiments, the supplementary material will have an affinity for calcium, phosphate or calcium phosphates which will enhance the strength of the PCA calcium phosphate/supplementary material interface. The affinity will be specific or mediated through non-specific ionic interactions. By

> way of example only, suitable biorerodible polymers for use as a matrix in the composite include, but are not limited to, collagen, glycogen, chitin, celluloses, starch, keratins, silk, nucleic acids, demineralized bone matrix, derivativized hyaluronic acid, polyanhydrides, polyorthoesters, polyglycolic acid, polylactic acid, and copolymers there of. In particular, polyesters of α-hydroxycarboxylic acids, such as poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly (lactide-co-glycolide) (PLGA), poly(D,L-lactide-co-trimethylene carbonate), and polyhydroxybutyrate (PHB), and polyanhydrides, such as poly(anhydride-co-imide) and co-polymers thereof are known to bioerode and are suitable for use in the present invention. In addition, bioactive glass compositions, such as compositions including SiO_2, Na_2O, CaO, P_2O_5, Al_2O_3 and/or CaF_2 may be used in combination with the PCA calcium phosphate of the invention. Other useful bioerodible polymers may include polysaccharides, peptides and fatty acids.

Page 37, line 9 - page 38, line 26. Thus, one of ordinary skill would understand the meaning of "supplemental materials" from simply reading Applicants' specification. Accordingly, Applicants respectfully submit that the claim term "supplemental," as used in the pending claims, satisfies the requirements of 35 U.S.C. § 112, ¶2.

The Office Action, without specifying which claims, objects to Applicants' use of the claim term "selected." Applicants presume that this rejection does not apply to claims in Markush format, which have been acceptable since at least 1925. *See* MPEP § 2173.05(h). Furthermore, Applicants respectfully submit that other uses of the word "selected" are sufficiently definite to satisfy the requirements of 35 U.S.C. § 112, ¶2. For example, claim 42 recites, in part, "said supplemental material present in an amount effective to impart a *selected characteristic* to the composite" (emphasis added). The present application makes clear that:

> The supplemental material is selected based upon its compatibility with calcium phosphate and its ability to impart properties (biological, chemical or mechanical) to the composite, which are desirable for a particular therapeutic purpose. For example, the supplementary material may be selected to improve tensile strength and hardness, increase fracture toughness, alter elasticity, provide imaging capability, and/or alter flow properties and setting times of the PCA calcium phosphate.

Page 37, lines 15-22.

The only other use of the word "selected" in the pending claims is either in "said promoter selected to promote the conversion of the calcium phosphate into a strongly resorbable,

poorly crystalline apatitic calcium phosphate" or "said promoter selected to convert the mixed powders into a poorly crystalline apatitic calcium phosphate." Once again, after reading Applicants' specification, it is abundantly clear that the promoter recited in the claim converts or promotes the conversion of either calcium phosphate or the mixed powders. One of ordinary skill, having read Applicants' specification, would clearly understand this claim term. Accordingly, Applicants respectfully submit that the claim term "selected," as used in the pending claims, satisfies the requirements of 35 U.S.C. § 112, ¶2.

The Office Action has also objected to the use of the word "characteristic," on the basis that this word is "indefinite, ambiguous, or relative" and fails "to impart specificity to permit identification of the meets [sic] and bounds of the subject matter of the invention as claimed." Office Action at 3. Applicants respectfully submit that the word "characteristic," as used in the pending claims is sufficiently definite to satisfy the requirements of 35 U.S.C. § 112, ¶2. Specifically, claim 42 refers to "said supplemental material present in an amount effective to impart a *selected characteristic* to the composite" (emphasis added). As discussed in detail above, the characteristics that one of skill in the art are made abundantly clear in the specification. *See, e.g.*, page 37, lines 15-22. Thus, one of ordinary skill would understand the meaning of this claim term from simply reading Applicants' specification. Accordingly, Applicants respectfully submit that the claim term "characteristic," as used in the pending claims, satisfies the requirements of 35 U.S.C. § 112, ¶2.

Applicants have amended claim 103 by deleting the word "suitable." Accordingly, the rejection based on this claim term is now moot.

Applicants have amended claims 111 and 129 to replace "associated with" with "characterized by." Accordingly, the rejection based on this claim term is now moot.

The Office Action objected to the term "derivativized," which appeared in claims 121, 135, and 146 only, even though these claims were withdrawn from consideration. Nevertheless, Applicants have amended claims 121, 135, and 146, rendering this ground of rejection moot.

Applicants have amended claim 111 to rectify the antecedent basis. Accordingly, this rejection may be withdrawn.

Therefore, Applicants respectfully submit that all pending claims satisfy the requirements of 35 U.S.C. § 112, ¶2.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 40, 42, 43, 103, 111-120, 122-134, 136-143, 145,147, and 148 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As grounds for this rejection, the Office Action summarily states:

> One or ordinary skill in bioceramic arts would not know how and what to prepare and under what condition, in order to arrive at the claimed, poorly identified, compositions, composites and method. It is not clear how pressing is done in vivo (claim 113).

Office Action at 3.

Claim 113 has been amended to recite that the "hydrating is carried out *in vivo*." Applicants respectfully submit that this clarifying amendment serves also to satisfy the requirements of 35 U.S.C. § 112, ¶1.

With respect to the remaining claims rejected under 35 U.S.C. § 112, ¶1, Applicants further submit that the claim amendments made above, in combination with the fifty-two examples and extensive description, remedy any concerns the Examiner may have had concerning the enablement of the pending claims. If the Examiner believes that any of the pending claims do not satisfy the requirements of 35 U.S.C. § 112, ¶1, Applicants request that the specific claim(s) and grounds for the rejection(s) be identified and explained.

Claim Rejections under 35 U.S.C. § 102

Claims 40, 42, 103, 111-114,116-118,120,122,124,126-131, 133, 134, 136, 138-145, 147, and 148 stand rejected under 35 U.S.C. 102(e) as being allegedly anticipated by U.S. Patent No. 5,782,971 to Constantz *et al.* ("the Constantz '971 patent").

The teachings of the Constantz '971 patent cited by the Examiner are not prior art. For the Constantz '971 patent to constitute prior art, it must have a filing date earlier than the effective filing date of the present application. MPEP § 706.02(a); 35 U.S.C. § 102(e). The present application claims priority to three applications filed on October 16, 1996. The filing date of the Constantz '971 patent is March 19, 1997, which is after the effective filing date of the present application. Although the Constantz '971 patent claims priority from earlier applications that were filed before May 20, 1996, those applications do not contain the pertinent teachings relied upon by the Examiner.

Furthermore, even if the Constantz '971 patent were available as prior art, it would not anticipate the claimed invention. The Office Action points to various features of the Constantz specification relating to the composition and reaction conditions of the calcium phosphate material as being relevant to the claimed invention. See, page 4 of the Office Action. Applicants respectfully disagree.

The Constantz '971 patent is clearly directed to a calcium phosphate cement and does not teach or suggest a compressed powder article. The invention is described in the Summary of the Invention as follows:

> The subject compositions comprise amorphous calcium phosphate and at least one additional calcium source, usually at least one additional calcium phosphate source, as well as a physiologically acceptable lubricant. Combination of the various components of the subject compositions produces a *flowable, paste-like material* capable of setting in vivo into a remodelable calcium phosphate, usually apatitic, product (emphasis added).

Column 2, lines 27-34.

There is no teaching of pressing of powders of calcium phosphate and a promoter into a compress object of a predetermined shape, as is recited in each of the pending claims. The

Office Action notes that "pressing and mixing" are taught "at Col. 8, B.". A careful reading of column 8 at section B reveals only reference to powder preparation techniques involving grinding and mixing of precursor powders, e.g.:

> Into a mortar is introduced 8.60 mg of milled base comprising 222.02 g $Ca_4(PO_4)_2O$, 0.085 g of calcium oxide, and 27.13 g $CaCO_3$ (Cement B). After grinding for 15 sec. 1.40 g H_3PO_4 are added and ground for 30 seconds. 5.0 g of Example 1.B ACP colloid [ACP + lubricant] are added and the mixture [paste] vigorously agitated with a pestle for 3 min. The paste is scraped from side of the pestle with a spatula to maintain the mixture in the center. The mixture is then ready for use.

Column 8, lines 24-31. This passage clearly refers to a paste composition. Thus, a pressed powder object is not suggested in any of the Constantz '971 disclosure. Formation of a poorly crystalline hydroxyapatite article by hydration of a pressed powder object proceeds in a fundamentally different manner than the reaction of a paste composition. Thus, the Constantz '971 patent does not anticipate or render obvious the claimed invention.

In summary, since the teachings of Constantz cited by the Examiner do not predate the effective filing date of the present application, these teachings do not constitute prior art and cannot be relied upon by the Examiner in issuing a rejection. Furthermore, the Constantz '971 patent does not teach or suggest the claimed invention. Therefore, Applicants respectfully request that the Examiner withdraw this rejection.

Claim Rejections under 35 U.S.C. §102(b)/103(a)

Claims 40, 42, 43, 103, 111-114, 116-120 , 122-134, 136-145, 147 and 148 stand rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 4,880,610 to Constantz (the "Constantz '610 patent").

The Office Action points to various features of the Constantz specification relating to the composition and reaction conditions of the calcium phosphate material as being relevant to the claimed invention. See, page 5 of the Office Action. Applicants respectfully disagree.

The Constantz '610 patent discloses paste compositions consisting of a phosphoric acid source, a calcium source and water. The resultant paste is shaped, and the paste hardens into a

final product. See, col 2, lines 32-42. There is no teaching of pressing of powders of calcium phosphate and a promoter into a compressed object of a predetermined shape, as is recited in each of the pending claims. The Office Action notes that "mixing, shaping and packing is taught" at column 5. A careful reading of column 5 reveals only reference to paste compositions, e.g.,

> "The product is formed by *combining* the dry ingredients, either separately or pre-mixed, with the phosphoric acid and aqueous media, base protein, and other additives, as appropriate. The *mixture* is thoroughly mixed over a relatively short time, so as to thoroughly distribute all of the reactants. Once the mixture is uniformly dispersed, the mixture may then be kneaded, continuing the process of reaction, releasing any gas which is formed, and *shaping* the product into an appropriate form. The kneading is over a relatively short time, usually not less than about 0.5 minutes and not more than about 2 minutes. Where the product is to be introduced in situ, it may be injected into the appropriate site, using a syringe or catheter, or *packed* in by other means, as appropriate." (Emphasis added).

Col. 5, lines 18-33. This passage clearly refers to a paste composition. Thus, a pressed powder object is not suggested in any of the Constantz disclosure. Formation of a poorly crystalline hydroxyapatite article by hydration of a pressed powder object proceeds in a fundamentally different manner than the reaction of a paste composition. Thus, the Constantz '610 patent does not anticipate or render obvious the claimed invention. Therefore, Applicants respectfully submit that this rejection should be withdrawn.

Claim Rejections under 35 U.S.C. § 103(a)

Claims 40, 42, 103, 111-120, 122-134, 136-145, 147, and 148 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Constantz `971 patent in view of U.S. Patent No. 4,880,610 to Constantz ("the Constantz '610 patent") and Fukase *et al.*

As discussed above, the teachings of the Constantz `971 patent, cited as the primary bases for this rejection, are not prior art; nor do they teach or suggest the claimed invention. The teachings of the secondary references cannot compensate for the absence of the primary reference. Therefore, Applicants respectfully submit that this rejection should be withdrawn.

Claim Rejections under 35 U.S.C. § 102(e)

Claims 40, 42, 111-120, 126-134, 138-145, 147, and 148 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Brown et al 6,201,039 B1 (the "Brown '039 patent").

As the sole basis for this rejection, the Office Action states:

> See summary, Examples.

Office Action at 6.

Applicants respectfully submit that this rejection is improper as not informative. *See* MPEP § 707.07(d). Nothing in this rejection indicates how any one of the twenty-nine claims are anticipated by the Brown '039 patent.

Furthermore, a reference must teach each and every limitation of the claimed invention in order for the claim to be anticipated. There is not a single statement or suggestion in the Brown '039 patent of pressing powders to form a compressed object of a predetermined shape prior to hydration. Thus, the rejection should be withdrawn.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance if an interview with Applicant's attorney would expedite prosecution, the Examiner is invited to call the undersigned at 617-428-0200. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

If there are any charges or any credits, please apply them to Deposit Account No. 08-0219.

Respectfully submitted,

Date: August 1, 2002

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Version with Markings to Show Changes Made

40. (Twice Amended) A method of preparing a bioceramic composition, comprising:

mixing powders of a calcium phosphate and a promoter;

pressing the powders to form a compressed object [powder compact] of a predetermined shape; and

hydrating the compressed object [powder compact] to form a reaction product, the reaction product comprising a poorly crystalline apatitic calcium phosphate.

42. (Amended) A composite material, comprising:

a strongly bioresorbable, poorly crystalline apatitic calcium phosphate in [intimate] contact with a biocompatible supplemental material, said supplemental material present in an amount effective to impart a selected characteristic to the composite.

43. (Twice Amended) A bioceramic composition comprising:

a compressed powder object [compact] of a predetermined shape comprising powders of a calcium phosphate and a promoter, said promoter selected to promote [the] conversion of the calcium phosphate into a strongly bioresorbable [resorbable], poorly crystalline apatitic calcium phosphate.

103. (Twice Amended) A method for treating a bone defect comprising:

identifying a bone site [suitable] for receiving an implant;

introducing a pressed powder object [compact] at the bone site, said pressed powder object [compact comprised of] comprising a calcium phosphate and a promoter and having approximately the shape required for repair of the bone defect, whereby the pressed powder

object [compact] is converted in vivo into a strongly bioresorbable [resorbable] poorly crystalline apatitic calcium phosphate.

111. (Amended) The method of claim 40 wherein said hydrating [conversion] is [associated with] characterized by an endothermic reaction.

112. (Amended) The method of claim 40 wherein said hydrating [conversion] further comprises [incubation of the hydrated compact] incubating the compressed object at about 37 °C.

113. (Amended) The method of claim 40 wherein said hydrating [conversion] is carried out *in vivo*.

114. (Amended) The method of claim 40, wherein [a hydration media for] said hydrating comprises using a hydration medium to hydrate the compressed object, [powder compact] wherein said hydration medium is selected from the group consisting of physiological fluids, [and] serum culture medium, and tissue culture medium.

115. (Amended) The method of claim 40, further comprising lyophilizing the reaction product [poorly crystalline apatitic calcium phosphate powder compact].

118. (Amended) The method of claim 40, wherein the promoter is selected from the group consisting of calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, tricalcium phosphates, calcium pyrophosphate dihydrate, crystalline hydroxyapatite, PCA calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, $CaC0_3$, calcium acetate, and H_2PO_4, and amorphous calcium phosphate.

120. (Amended) The method of claim 40 further comprising the step of mixing a supplemental material with the powders.

121. (Amended) The method of claim 120 wherein the supplemental material is [selected from the group consisting of collagen,] demineralized bone[, derivativized hyaluronic acid, polylactic acid, poly (L-lactide) (PLLA), poly (D,L-lactide) (PDLLA), polyglycolide (PGA),

poly (lactide-co-glycolide) (PLGA), dextrans, polyethylene, polymethylmethacrylate (PMMA), carbon fibers, polyvinyl alcohol (PVA), poly (ethylene terephthalate)polyamide, bioglasses, calcium sulfate and calcium phosphates].

123. (Amended) The method of claim 40 wherein said poorly crystalline apatitic (PCA) calcium phosphate is further characterized in that when at least one gram of said poorly crystalline apatitic (PCA) calcium phosphate is impanted at [placed in] a rat intramuscular site, [resorption of at least 1 g of the material is] at least 80% of said poorly crystalline apatitic (PCA) calcium phosphate is resorbed within one year.

125. (Amended) The method of claim 43[40] wherein said poorly crystalline apatitic (PCA) calcium phosphate is further characterized in that when at least one gram of said strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate is implanted at [placed in] a rat intramuscular site, [resorption of at least 1 g of the material is] at least [80%] 90% of said strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate is resorbed within one year.

127. (Amended) The composition of claim 43 wherein the object further comprises [comprising] a hydration medium [media] to hydrate the object [powder compact, wherein the hydrated powder compact converts to the poorly crystalline apatitic calcium phosphate].

128. (Amended) The composition of claim 127 wherein the hydration medium [media for hydrating the powder compact] is selected from the group consisting of physiological fluids, [and] serum culture medium, and tissue culture medium.

129. (Amended) The composition of claim 127 wherein said conversion is [associated with] characterized by an endothermic reaction.

133. (Amended) The composition of claim 43, wherein the promoter is selected from the group consisting of calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, tricalcium phosphates, calcium pyrophosphate dihydrate, crystalline

hydroxyapatite, PCA calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, $CaC0_3$, calcium acetate, and H_3PO_4, and amorphous calcium phosphate.

135. (Amended) The composition of claim 134 wherein the supplemental material is [selected from the group consisting of collagen,] demineralized bone[, derivativized hyaluronic acid, polylactic acid, poly (L-lactide) (PLLA), poly (D,L-lactide) (PDLLA), polyglycolide (PGA), poly (lactide-co-glycolide) (PLGA), dextrans, polyethylene, polymethylmethacrylate (PMMA), carbon fibers, polyvinyl alcohol (PVA), poly (ethylene terephthalate)polyamide, bioglasses, calcium sulfate and calcium phosphates].

137. (Amended) The composition of claim 127 wherein said poorly crystalline apatitic calcium phosphate is further characterized in that when at least one gram of said strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate is implanted at [placed in] a rat intramuscular site, [resorption of at least 1 g of the material is] at least [80%] 90% of said strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate is resorbed within one year.

139. (Amended) The method of claim 138, further comprising incubating [wherein said hardening comprises incubation of] the paste at about 37 °C.

140. (Amended) The method of claim 138, wherein [a hydration media for] the hydrating medium [the powder compact] is selected from the group consisting of water, physiologically acceptable pH-buffered solutions, saline solution, [and] serum culture medium, and tissue culture medium.

141. (Amended) The method of claim 138, further comprising lyophilizing the [molded poorly crystalline apatitic calcium phosphate] article.

144. (Amended) The method of claim 138, wherein the promoter is selected from the group consisting of calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, tricalcium phosphates, calcium pyrophosphate dihydrate, crystalline

hydroxyapatite, PCA calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, $CaCO_3$, calcium acetate, and H_2PO_4, and amorphous calcium phosphate.

146. (Amended) The method of claim 145 wherein the supplemental material is [selected from the group consisting of collagen,] demineralized bone[, derivativized hyaluronic acid, polylactic acid, poly (L-lactide) (PLLA), poly (D,L-lactide) (PDLLA), polyglycolide (PGA), poly (lactide-co-glycolide) (PLGA), dextrans, polyethylene, polymethylmethacrylate (PMMA), carbon fibers, polyvinyl alcohol (PVA), poly (ethylene terephthalate)polyamide, bioglasses, calcium sulfate and calcium phosphates].